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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/053,872	04/01/98	ROSE E	50634BJPWJML

HM22/1105

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EXAMINER	
RUSSEL,J	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 11/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/053,872	E. Rose et al
Examiner	**Group Art Unit**
J. Russel	1653

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 2-9-1999 and 9-27-2001.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disp sition of Claims

☒ Claim(s) 23-57 is/are pending in the application.

Of the above claim(s) 23-37, 40, 41, 43-45, and 47-57 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 38, 39, 42, and 46 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

1. Claims 23-37 and 52-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Claims 40, 41, 43-45, and 47-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. It is noted that Applicants did not list all claims which are readable on the elected species as required in the election of species requirement.

Applicant's election with traverse of the invention of Group I, claims 38-51, in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the Groups are not independent of one another because all of the groups relate directly to Factor IXa. This is not found persuasive because the groups are drawn to different statutory classes of invention as set forth in the restriction requirement. If Applicants' analysis were to be accepted, then a product could never be restricted from a method of using the product, and this result is contrary to established restriction practice. Applicants also contend that restriction is improper if no serious burden would be imposed by examining all of the claims. However, as set forth in the restriction requirement, a serious burden would be imposed upon the examiner because of the additional searching requirements in examining an assay and a therapeutic method. For example, the Lenting et al article applied below underscores the different issues involved in examining products and their methods of use. The Lenting et al article anticipates Applicants' claimed compositions but is insufficient to anticipate or suggest Applicants' claimed therapeutic method because the

Lenting et al article does not disclose any in vivo utility for the inactivated Factor IXa. Further searching related to therapeutic methods of use of inactivated Factor IX would be required, and this constitutes an undue burden upon the examiner.

The requirement is still deemed proper and is therefore made FINAL.

2. The drawings are objected to because in Figure 5A, "CaCL" should be "$CaCl_2$". Correction is required.

Applicant is required to submit a proposed drawing correction in response to this Office action. Any proposal by Applicant for amendment of the drawings to cure defects must consist of two parts:

a) A separate letter to the Draftsperson in accordance with MPEP 608.02(r); and

b) A print or pen-and-ink sketch showing changes in red ink or with the changes otherwise highlighted in accordance with MPEP 608.02(v).

IMPORTANT NOTE: The filing of new formal drawings to correct the noted defect(s) may be deferred until the application is allowed by the examiner, but the print or pen-and-ink sketch with proposed corrections shown in red ink or with the changes otherwise highlighted is required in response to this Office action, and *may not be deferred.*

The drawings filed April 1, 1998 were otherwise approved by the draftsman for matters of form.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However,

this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

Nucleotide sequences are present at pages 13-14 of the specification which are subject to the sequence disclosure rules, but no sequence listing has been submitted. Further, SEQ ID NOS must be inserted after every sequence subject to the sequence disclosure rules. See 37 CFR 1.821(d).

Applicant must provide an original computer readable form (CRF) copy of the Sequence Listing, a substitute paper copy of the Sequence Listing as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and include no new matter as required by 37 CFR 1.825(a) and (b).

4. The disclosure is objected to because of the following informalities: At page 1, line 8, the status of the U.S. patent application should be updated. At page 6, line 21, "congenital" is misspelled. Appropriate correction is required.

5. Claims 39, 42, and 46 are objected to because of the following informalities: At claim 39, line 4, "Ixai" should be changed to "IXai". At claim 42, line 5, "Aly" should be changed to "Gly". At claim 42, page 3 of the amendment filed February 9, 2001, line 5, "antibody" should be inserted after "monoclonal". At claim 46, line 4, "Ixa" should be changed to "IXa". Appropriate correction is required.

6. Claims 42 and 46 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to

cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The factor IXa compounds recited in instant claims 42 and 46 are not species of the recombinant muteins required by claim 40, upon which claims 42 and 46 depend. Claim 42 also does not further limit independent claim 38 because claim 42 recites competitive inhibitors and antibodies which are not species of the chemically modified forms and recombinant muteins required by claim 38, upon which claim 42 ultimately depends.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 38, 39, 42, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by the Benedict et al article (J. Clin. Invest., Vol. 88, pages 1760-1765). The Benedict et al article teaches an aqueous saline solution comprising bovine Factor IXa inactivated with Glu-Gly-Arg-chloromethylketone. The composition is used as a thrombosis inhibitor. See, e.g., the Abstract; page 1760, column 2, first full paragraph; and Table 1.

9. Claims 38, 39, 42, and 46 are rejected under 35 U.S.C. 102(a) as being anticipated by the Wong et al abstract (Suppl. I Circ., Vol. 92, page I-686). The Wong et al abstract teaches a bolus form of dansyl Glu-Gly-Arg chloromethyl ketone-inactivated bovine Factor IXa.

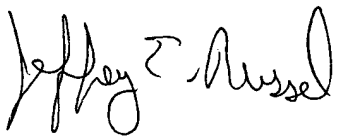
10. Claims 38, 39, 42, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by the Bajaj et al article. The Bajaj et al article teaches an aqueous composition comprising human Factor IXa inactivated with dansyl Glu-Gly-Arg-chloromethyl ketone. See, e.g., page 153, column 1, first full paragraph. Note with respect to the term "pharmaceutical", an intended use limitation does not impart patentability to product claims which are otherwise anticipated by the prior art, and the Bajaj et al article teaches every component required to be present by Applicants' claims.

11. Claims 38, 39, 42, and 46 are rejected under 35 U.S.C. 102(a) as being anticipated by the Lenting et al article. The Lenting et al article teaches an aqueous composition in which human Factor IXaβ, i.e. Factor IXa, is reacted with Glu-Gly-Arg-chloromethyl ketone. See, e.g., page 14884, column 2, second paragraph; page 14885, column 1, last paragraph; and Figure 2. Note with respect to the term "pharmaceutical", an intended use limitation does not impart patentability to product claims which are otherwise anticipated by the prior art, and the Lenting et al article teaches every component required to be present by Applicants' claims.

12. U.S. Patent No. 5,839,443 is cited as art of interest, but does not raise any obviousness-type double patenting issues.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Christopher Low can be reached at (703) 308-2923. The fax number for Art Unit 1653 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1653

JRussel

November 3, 2001